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REMARKS

Claims 1-33 are pending in the application. Claims 1, 4, 6-9, and 11-31 have been amended herein. No new matter is added by the amendments.

Rejections under 35 U.S.C. § 101

Claims 14, 22, and 28 were rejected under 35 U.S.C. § 101 as being directed to unpatentable subject matter. While Applicants do not concede that the claims as filed contain any unpatentable subject matter, Applicants have amended claims to recite "computer-readable medium" and "computer-readable instructions". Applicants respectfully request withdrawal of the rejection.

Applicants note the Examiner's advice to cancel claim 27. As no support is provided for the advice, and the advice is not a rejection, Applicants respectfully decline to cancel claim 27 in response to the advice.

Rejections under 35 U.S.C. § 103

I. Claims 1-5, 10, 14-18, 22-23, and 27-30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Krause et al. (U.S. Patent No. 6,701,174, hereinafter "Krause") in view of Clough (U.S. Patent No. 5,977,979). Applicants respectfully submit that claims 1-5, 10, 14-18, 22-23, and 27-30 as amended would not have been obvious in view of the cited references.

Krause describes a computer-implemented method of planning bone distraction. Krause is not concerned with prostheses and prosthetic implants such as artificial hips and knees. Instead, it is concerned with reconstructive bone surgery that involves cutting through a bone, attaching an external adjustable frame to the bone by wires passing through the flesh, and adjusting the frame to pull the parts of the bone apart slowly to encourage bone growth across the gap so as to extend and/or reshape the bone. The success of such a procedure depends on how the frame is fitted and subsequently adjusted. Thus, Krause relates to an entirely different problem than the present invention.

The Examiner refers to column 21, line 17 of Krause as justification that Krause discloses operations involving orthopaedic prostheses. However, this is a single isolated mention of prosthetic implants with no explanation of how the described method of

planning bone distraction would be applied to planning orthopaedic prosthesis implantation.

The method of Krause involves providing two orthogonal X-ray images of a bone to a computer with a view to generating a three-dimensional model of the imaged bone. This is done by extracting the contours or boundaries of the bone from the two images. (either automatically or indicated by a user viewing the images). The contours are projected out from the orthogonal images so that they intersect and define a closed volume that closely matches the actual volume of the bone. This volume information is used to select a template from a database of 3D template bone models. The template bone model is then scaled and positioned until its contour or boundary is considered to be optimum with respect to the real bone boundaries from the X-ray images. Then the scaled, updated template bone model is subjected to a computerized deformation process to deform it until it matches the actual patient's bone. This, a 3D model of the patient's bone is obtained. This model is then used to perform computer simulation and planning of the bone distraction procedure, so that the surgeon can determine how to position and adjust the external frame to achieve the desired bone reconstruction.

It would appear that the Examiner is equating the model of Krause (at least including the production of the 3Dmodel of the patient's bone) with the present invention. However, Krause and Clough each lack claimed features of the present invention, as detailed below. The claims are directed to a computer-implemented method for planning orthopaedic surgery. For example, the claimed invention is applicable to the fitting of prosthetic implants such as artificial hip and knee joints. It is important for the success of such an operation that a properly sized prosthesis be used. Digital templates of the available prostheses are provided within an electronic library or database, the templates being two-dimensional representations of the prosthetic components. The system displays a patient image such as an X-ray, showing the appropriate anatomical parts relevant to the operation. The image is scaled or calibrated to compensate for the magnification often inherent in an X-ray image, where the user inputs information to achieve the correct scaling. Then, a geometrical construct (a "wizard") is displayed over the image. The wizard comprises interrelated shapes and lines appropriate for measuring the relevant parts

of the patient's anatomy (bone structure). The user manipulates or reconfigures the wizard by reshaping and repositioning the various shapes and lines to best match the relevant parts of the bones in the image. The sizes and angles of the shapes and lines indicate the measurements needed to choose an appropriate prosthesis of the correct size. The wizard is specifically adapted and structures to allow information most important to the particular type of prosthesis being fitted to be complete, the geometric parameters (measurements) indicated by the wizard are used by an algorithm that automatically selects one or more templates from the data base, the templates representing those prostheses that are considered most suitable for the patient based on the measurements from the image of the wizard.

Considering claim1 feature by feature:

providing a library of templates representing orthopaedic prostheses

The Examiner equates this with Krause's database of 3D template bone models (feature 54). Krause's templates are 3D models of bones which are intended to be deformed by computer processing to produce a model of an actual patient bone for use in surgery planning. The templates of claim 1 are two-dimensional representations of orthopaedic prostheses which are merely selected from the database by an algorithm, and undergo no computer deformation. Indeed they should not be processed in such a way because they represent real prosthetic components and the aim of the method is to identify the best prosthesis available.

displaying a patient image showing anatomical features that are relevant for the orthopaedic surgery being planned

Krause (column 11, lines 62-67) requires two orthogonal images.

scaling the patient image according to user input;

This feature is not found in Krause, as acknowledged by the Examiner.

displaying over the patient image a geometrical construct comprising a plurality of interrelated shapes and lines defined by a plurality of interrelated geometric parameters

Krause does not teach or suggest any such geometric construction being displayed over the patient image, in particular no geometrical construct with the features and functionality of the construct of the claimed invention. The Examiner points to Krause, column 12, lines 32-35: "The resultant 3D template bone model is shown in Figure 8, which displays the undeformed 3D template model with the patient's bone geometry reconstructed thereon." This is clearly not a geometrical construct displayed over the patient image, but is rather the patient's bone geometry (taken from the patient image) reconstructed onto the 3D template bone model taken from the database to produce an updated ("resultant") 3D template bone model.

Also, the Examiner refers to Krause, column 12, lines 21-29: "After detecting the bone contour at step 86, module A first identifies (at step 88) the corresponding fiducial geometry on the 3D template bone model prior to any deformation discussed hereinbelow. Module A also optimizes (at steps 90 and 92) the 3D positioning and scaling parameters for the 3D template bone model until the size and position of the 3D template bone model is optimum with respect to the patient's bone (as judged from the X-ray images 65, 66 of the patient's bone)" as an example of *a plurality of interrelated parameters*. However, the 3D positioning and scaling parameters of Krause are not described as being interrelated geometric parameters and they clearly do not define a geometrical construct displayed over the patient image as required by claim 1.

allowing a user to reconfigure the geometrical construct by adjusting the geometric parameters according to the anatomical features of the underlying patient image
geometrical construct (comprising a plurality of interrelated shapes and lines defined by a plurality of interrelated geometric parameters) by adjusting the geometric parameters according to the anatomical features of the underlying patient image

Continuing with the erroneous idea that positioning and scaling parameters of Krause are a geometrical construct displayed over the patient image according to claim 1, the Examiner points to Krause, column 12, lines 30-32: "Upon finding the optimum values for the positioning and scaling parameters, module A updates the 3Dtemplate bone model with new positioning and scaling parameters". Although the parameters are changed, there

is no teaching regarding reconfiguring of a geometrical construct (comprising a plurality of interrelated shapes and lines defined by a plurality of interrelated geometric parameters) by adjusting the geometric parameters according to the anatomical features of the underlying patient image. Furthermore, Krause clearly does not teach a geometrical construct displayed over the patient image.

The Examiner acknowledges that the method of Krause is automated whereas claim 1 states that the user is allowed to reconfigure the geometrical construct. The Examiner is of the view that it would be obvious to substitute manual adjustment for the automated "reconfiguration process" of Krause (the Examiner does not make clear what he considers to be reconfigured in Krause's method). This is incorrect. Krause's method is computer-intensive processing of a generic virtual bone model to produce a virtual model of an actual patient bone; this could not reasonably be performed manually. The present invention, in contrast, recognises that for the very different problem of templating for the purposes of planning orthopaedic prosthesis surgery, the method can be greatly improved by allowing the surgeon to manually manipulate a computer-generated wizard for the purpose of determining measurements of the bone structure, thus utilising the surgeon's skill at reading a patient image while obtaining measurements with a computer-level of accuracy, followed by automatic selection of a prosthesis template from a large database by computer algorithm. This is much faster and more accurate than known methods involving a surgeon comparing a small range of plastic templates against the patient image. In the context of the present invention, automation or manual performance of the various steps are not obvious interchangeable alternatives.

automatically selecting at least one template from the library in accordance with the geometric parameters adjusted by the user

There is no teaching or suggestion of such a feature in Krause. As indicated above, the templates in Krause's database are 3D bone model templates, not templates representing orthopaedic prostheses. Moreover, there is no selection from the database in accordance with the geometric parameters adjusted by the user, not least because there are no geometric parameters that define a geometrical construct displayed over a patient

image.

The Examiner cites Krause, column 12, lines 35-36: "Module A may also update the 3D template geometry database with the optimum positioning and scaling parameter values". This is not a selection of a template from the database, but additional information to the database. As is clear from the lines preceding and following the above citation in Krause, the database can be updated to include a new 3D template bone model that is obtained by scaling and positioning the originally selected template bone model in the first stages of deforming the selected template bone model to make it match the patient's actual bone. In Krause, selection from the template database happens much earlier in the process, and a 3D template bone model is selected by reference to the volume defined by the swept bone boundaries of the orthogonal patient images (column 12, lines 4-20). This is clearly not selection of a prosthesis template in accordance with geometric parameters of a geometric construct displayed over the patient image that have been reconfigured by a user.

Overall, therefore, Krause fails to disclose, teach, or suggest the majority of the features of claim 1. Applicants respectfully submit that Clough does not supply the deficiencies of Krause, and the claimed invention does not result from the combination of the references.

The Examiner acknowledges that Krause does not teach scaling of the patient image according to the independent claims. Instead, he finds this feature in Clough. While Clough is related to scaling and images, it is concerned with two-dimensional simulation of three-dimensional scenes for display to a user, and relates to image processing and display, and not to computer-implemented planning of orthopaedic surgery (neither the bone distraction of Krause, nor the prostheses implantation of the present invention). The scaling described in Clough is the scaling of objects moving within the displayed scene so as to produce the correct size of the object with respect to its apparent distance from the viewer, and not scaling of patient images to correct for X-ray magnification. Clough is in an entirely different technical field from Krause, and the skilled person would not look to Clough to learn how to scale patient images, and moreover, would not be taught how to do so if he did. Therefore, one of ordinary skill

would find not motivation to combine the references to achieve the claimed invention.

Motivation to combine or modify Krause is further lacking because Krause (as explained above) discloses a bone distraction method that is not modifiable in any way that would result in the method of the present invention.

Moreover, as stated above, the proposed combination would not result in the claimed invention, at least because Krause fails to teach a computer-implemented method of planning orthopaedic surgery as in claim 1, and Clough fails to teach how to scale a patient image.

For all of these reasons, Applicants respectfully submit that claim 1 would not have been obvious to one of ordinary skill in the art at the time they were made. Claims 2-5 depend from claim 1 and include further limitations thereon. Therefore, claims 2-5 are allowable for the same reasons given with reference to claim 1.

Claim 10 depends from independent claim 9, which includes elements corresponding to each of the elements discussed with reference to claim 1. Therefore, Applicants respectfully submit that claim 10 (which include limitations in addition to those of claim 10) is allowable over Krause and Clough.

Independent claim 14 includes similar limitations to those discussed with reference to claim 1. Therefore, Applicants respectfully submit that claim 14 and its dependent claims 15-18 are allowable over Krause and Clough.

Independent claim 22 includes similar limitations to those discussed with reference to claim 1. Therefore, Applicants respectfully submit that claim 22 and its dependent claims 23, 27 and 28 are allowable over Krause and Clough.

Independent claim 29 includes similar limitations to those discussed with reference to claim 1. Therefore, Applicants respectfully submit that claim 29 and its dependent claim 30 are allowable over Krause and Clough.

II. Dependent claims 6-8, 11-13, 19-21, and 24-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Krause in view of Clough, and further in view of Tanaka (U.S. Patent No. 6,692,448). Tanaka is cited as teaching an artificial bone template selection method that includes geometric parameter that are adjusted according to

anatomical features of a femur so as to allow selection of a template representing a femoral component of a hip prosthesis.

However, Applicants respectfully submit that Tanaka does not disclose selection in accordance with geometric parameters of a geometrical construct displayed over a patient image and reconfigured by a user according to the anatomical featured shown in the image. In addition, as discussed above, the invention of the independent claims would not have been obvious in view of the combination of Krause and Clough. Further, the combination of Krause and Clough does not result in the claimed invention. As Tanaka does not supply the stated deficiencies of either Krause or Clough, the combination of the three references does not result in the invention of claims 6-8, 11-13, 19-21, or 24-26. For all of these reasons, Applicants respectfully submit that claims 6-8, 11-13, 19-21, and 24-26 would not have been obvious in view of the cited references.

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CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the claims as amended are allowable over the prior art. Applicants respectfully request allowance of all of the pending claims and respectfully request the Examiner to phone the undersigned if it would facilitate such allowance.

AUTHORIZATION TO CHARGE DEPOSIT ACCOUNT

Please charge deposit account 503616 for any fees due, and not paid herewith, in connection with this Office action response.

Respectfully submitted,
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